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UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS P.O. Box 1450 Alexandria, Virginia 22313-1450

NOTICE OF ALLOWANCE AND FEE(S) DUE

23492

7590

05/07/2003

STEVEN F. WEINSTOCK ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008 EXAMINER

HESS, DANIEL A

ART UNIT CLASS-SUBCLASS

356-039000

2876

DATE MAILED: 05/07/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874 493	06/05/2001	Ronny van't Oever	6811.US.O1	6161

TITLE OF INVENTION: OPTICAL METHOD AND APPARATUS FOR RED BLOOD CELL DIFFERENTIATION ON A CELL-BY-CELL BASIS, AND SIMULTANEOUS ANALYSIS OF WHITE BLOOD CELL DIFFERENTIATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO ,	\$1300	\$300	\$1600	08/07/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED.</u> THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

Applicant claims SMALL ENTITY status.
 See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE Commissioner for Patents

Alexandria, Virginia 22313-1450

Fax (703)746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where

appropriate. All further co indicated unless corrected maintenance fee notificatio	below or directed otherwis	Patent, advance orders se in Block 1, by (a) sp	and notification ecifying a new co	of maintenance fee orrespondence addr	es will be mailed to the current ess; and/or (b) indicating a sep	correspondence address as arate "FEE ADDRESS" for	
CORRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)				Note: A certificate of mailing can only be used for domestic mailings of the			
23492 7590 05/07/2003				Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or			
STEVEN F. WE				formal drawing, r	must have its own certificate of r	nailing or transmission.	
ABBOTT LABOR				I hambu aastifu	Certificate of Mailing or Tran	smission	
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ABBOTT PARK,	IL 60064-6008			envelope address transmitted to the	ed to the Box Issue Fee address USPTO, on the date indicated b	above, or being facsimile below.	
						(Depositor's name)	
•						(Signature)	
						(Date)	
APPLICATION NO.	FILING DATE	FIRS	ST NAMED INVEN	TOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/874,493	06/05/2001		Ronny van't Oeve		6811.US.O1	6161	
TITLE OF INVENTION: SIMULTANEOUS ANAL				CELL DIFFERENT	TATION ON A CELL-BY-CE	LL BASIS, AND	
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nonprovisional	NO	\$1300		\$300	\$1600	08/07/2003	
EXAM	NER	ART UNIT	CLASS-SUBC	LASS			
HESS, DA	NIEL A	2876	356-03900	00			
1. Change of corresponder CFR 1.363).	nce address or indication of	"Fee Address" (37	the names of u	on the patent from p to 3 registered p alternatively, (2)	atent attorneys		
☐ Change of correspond Address form PTO/SB/1	ence address (or Change of 22) attached.	Correspondence	single firm (ha	aving as a member	er a registered		
	ion (or "Fee Address" Indic or more recent) attached. U		registered pater	ent) and the name at attorneys or ager are will be printed.			
3. ASSIGNEE NAME ANI	RESIDENCE DATA TO	BE PRINTED ON THE	PATENT (print o	or type)			
PLEASE NOTE: Unless a been previously submitted (A) NAME OF ASSIGNE	to the USPTO or is being	submitted under separate	e cover. Completion	patent. Inclusion of on of this form is No Y and STATE OR O	assignee data is only appropria of a substitute for filing an assign COUNTRY)	te when an assignment has gnment.	
Please check the appropriat	e assignee category or categ	pories (will not be printe	d on the patent)	🗅 individual	☐ corporation or other private g	roup entity	
4a. The following fee(s) are			yment of Fee(s):				
☐ Issue Fee		□ A cl	neck in the amoun	t of the fee(s) is end	closed.		
□ Publication Fee		🔾 Payı	ment by credit car	d. Form PTO-2038	is attached.		
☐ Advance Order - # of C	Copies	☐ The Denosi	Commissioner is it Account Number	hereby authorized b	by charge the required fee(s), or complete (conclose an extra copy of this	credit any overpayment, to	
Commissioner for Patents is	s requested to apply the Issu	<u>.</u>			asly paid issue fee to the applicat		
(Authorized Signature)		(Date)					
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other than the applicant;	d Publication Fee (if requ a registered attorney or a ecords of the United States	igent; or the assignee c	or other party in				
This collection of inform obtain or retain a benefit application. Confidentialitiestimated to take 12 minu completed application for case. Any comments on	ation is required by 37 CF by the public which is to by is governed by 35 U.S.C. utes to complete, including m to the USPTO. Time v the amount of time you this burden, should be sen Office, U.S. Department SEND FEES OR COMPL	R 1.311. The information file (and by the USPT) 122 and 37 CFR 1.14. gathering, preparing, an will vary depending upon require to complete to	on is required to O to process) an This collection is d submitting the on the individual his form and/or	·		·	
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09/874,493	06/05/2001	Ronny van't Oever	6811.US.O1	6161
23492	7590 05/07/2003	·	EXAMINE	SR .
STEVEN F. W	EINSTOCK		HESS, DAN	IEL A
ABBOTT LABO			ART UNIT	PAPER NUMBER
DEPT. 377/AP6	: -		2876	
ABBOTT PARK	., IL 60064-6008		DATE MAII ED: 05/07/2002	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The patent term adjustment to date is 2 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 2 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.



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STEVEN F. W	/EINSTOCK	•	HESS, DAN	IIEL A
ABBOTT LAB			ART UNIT	PAPER NUMBER
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	K, IL 60064-6008		2876	
INITED CTAT			DATE MAILED: 05/07/2003	

Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003: Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: http://www.uspto.gov/main/howtofees.htm.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

<u> </u>			<u>/</u>
•	Application No.	Applicant(s)	
AL (* PAU . 1 ****	09/874,493	OEVER ET AL.	
Notice of Allowability	Examiner	Art Unit	
	Daniel A Hess	2876	
The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIPORT OF THE	(OR REMAINS) CLi or other appropriate IGHTS. This applica and MPEP 1308.	OSED in this application. If not include e communication will be mailed in due o ation is subject to withdrawal from issue	ed course. THIS
a) ☐ All b) ☐ Some* c) ☐ None of the:			
Certified copies of the priority documents have			
Certified copies of the priority documents have	been received in A	pplication No	
3. ☐ Copies of the certified copies of the priority do: International Bureau (PCT Rule 17.2(a)).	cuments have been	received in this national stage applicat	ion from the
* Certified copies not received:		0/ \/	
5. Acknowledgment is made of a claim for domestic priority un			
(a) The translation of the foreign language provisional a	• •		
6. Acknowledgment is made of a claim for domestic priority un	nder 35 U.S.C. 99 1	20 and/or 121.	
Applicant has THREE MONTHS FROM THE "MAILING DATE" of below. Failure to timely comply will result in ABANDONMENT of			
7. A SUBSTITUTE OATH OR DECLARATION must be submINFORMAL PATENT APPLICATION (PTO-152) which gives reas			OTICE OF
 8. CORRECTED DRAWINGS must be submitted. (a) including changes required by the Notice of Draftsper 1) hereto or 2) to Paper No. (b) including changes required by the proposed drawing of including changes required by the attached Examiner 	correction filed	_, which has been approved by the E	
Identifying indicia such as the application number (see 37 CFR 1 each sheet.	.84(c)) should be writ	ten on the drawings in the front (not the	back) of
9. DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT FOR T			lote the
Attachment(s)			
1☐ Notice of References Cited (PTO-892) 3☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5☐ Information Disclosure Statements (PTO-1449), Paper No 7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	4□ 6□ 8⊠	Notice of Informal Patent Application (FINTER) Interview Summary (PTO-413), Paper Examiner's Amendment/Comment Examiner's Statement of Reasons for A Other .	No

Application/Control Number: 09/874,493

Art Unit: 2876

DETAILED ACTION

1. Receipt is acknowledged of response dated 3/31/2003, which has been placed in the file of record, and to which this action is a reply.

REASONS FOR ALLOWANCE

- 2. Claims 1-21 are allowed. The following is a statement of the examiner's reasons for allowance.
- Re claims 1-12 and 21: The nearest available prior art of record, Tycko (US 5,194,909), shows (column 7, line 66; column 4, lines 65-70) the sphering of red blood samples using sphering reagent. The solution is (column 8, lines 8-15) a neutrally buffered saline solution (7.4 pH). Individual cells are 'entrained' (column 5, line 4). There is a 'stream' (column 15, line 51) of liquid containing the cells. Light of a particular color is shone on the cells (column 5, line 9; column 9, line 41). Tycko further shows that scattering measurements are taken at two particular angles (figures 4 and 5). These are 'forward scattering' measurements (column 5, lines 10-12). Tycko does show the use of plots to correlate the three variables of volume (V), HC and a scatter signal in figures 4 and 5, although he only shows this in two dimensions. However, in doing so, Tycko illustrates the principle of using gridded lines in a third variable to include 3 variables in 2 dimensions. Tycko also shows that a given measurement of scattering at a certain angle forms a single 'equation' for the variables of volume V and hemoglobin concentration HC (see figures 4 and 5). In figures 4 and 5, Tycko effectively shows two such equations.

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Tycko notably fails to teach or suggest "projecting a three-dimensional coordinate of light scatter signals from each cell onto a three-dimensional surface containing grid lines of V and HC."

Page 3

Nowhere else does the prior art of record teach or suggest the 3-dimensional analytical techniques claimed by the applicant for using a variety of scatter signals to obtain measurements of hemoglobin concentration and blood volume.

4. Re claims 13-20: The applicant's arguments regarding claim 13 in the action of 3/31/2003 were persuasive. The examiner agrees that certain elements taught in the prior art were lacking in Tycko as modified by Altendorf as applied to claim 13 of the previous action.

In particular, Tycko doesn't employ the same type of multi-angle light scattering as in the claimed invention. Further, as the applicant points out, large angle scattered light photo detectors are employed in Altendorf, and these are explicitly for Altendorf's white blood cell analysis. They are not designed to be dual-use.

The examiner did not find indication elsewhere in the prior art of record of teachings of the full limitations of claim 13.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel A Hess whose telephone number is (703) 305-3841. The examiner can normally be reached on 8:00 AM - 5:00 PM M-F.

Art Unit: 2876

- 6. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Lee can be reached on (703) 305-3503. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.
- 7. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

DH

May 2, 2003

Daniel A Hess Examiner Art Unit 2876

KARL D. FRECH PRIMARY EXAMINER